

**Claims**

1. A method for inducing an antigen specific response comprising:  
administering to a subject an antigen and a Th2-immunostimulatory nucleic acid in an  
amount effective to produce an antigen specific immune response when the Th2-  
5 immunostimulatory nucleic acid is administered mucosally or dermally.
2. The method of claim 1, wherein the subject is administered the antigen after the  
Th2-immunostimulatory nucleic acid.
- 10 3. The method of claim 1, wherein the subject is administered the antigen before the  
Th2-immunostimulatory nucleic acid.
4. The method of claim 1, wherein the subject is administered the antigen and the  
Th2-immunostimulatory nucleic acid simultaneously.
- 15 5. The method of claim 1, wherein the Th2-immunostimulatory nucleic acid is  
delivered to the mouth, skin or eye.
6. The method of claim 1, further comprising administering a therapeutic agent to the  
20 subject.
7. The method of claim 6, wherein the therapeutic agent is a Th1 adjuvant.
8. The method of claim 7, wherein the Th1 adjuvant is selected from the group  
25 consisting of CpG nucleic acids, MF59, SAF, MPL, and QS21.
9. The method of claim 7, wherein the Th1 adjuvant is administered following the  
administration of the Th2-immunostimulatory nucleic acid.
- 30 10. The method of claim 6, wherein the therapeutic agent is a Th2 adjuvant.
11. The method of claim 10, wherein the Th2 adjuvant is selected from the group  
consisting of adjuvants that create a depot effect, adjuvants that stimulate the immune system,

and adjuvants that create a depot effect and stimulate the immune system and mucosal adjuvants.

12. The method of claim 11, wherein the adjuvant that creates a depot effect is  
5 selected from the group consisting of alum; emulsion-based formulations including mineral oil, non-mineral oil, water-in-oil or oil-in-water-in oil emulsion, oil-in-water emulsions such as Seppic ISA series of Montanide adjuvants; and PROVAX.

13. The method of claim 11, wherein the adjuvant that stimulates the immune system  
10 is selected from the group consisting of saponins purified from the bark of the *Q. saponaria* tree; poly[di(carboxylatophenoxy)phosphazene; derivatives of lipopolysaccharides, muramyl dipeptide and threonyl-muramyl dipeptide; OM-174; and Leishmania elongation factor.

14. The method of claim 11, wherein the adjuvant that creates a depot effect and  
15 stimulates the immune system is selected from the group consisting of ISCOMs; SB-AS2; SB-AS4; non-ionic block copolymers that form micelles such as CRL 1005; and Syntex Adjuvant Formulation.

15. The method of claim 11, wherein the mucosal adjuvant is selected from the group  
20 consisting of CpG nucleic acids, Bacterial toxins, Cholera toxin, CT derivatives, CT B subunit; CTD53; CTK97; CTK104; CTD53/K63; CTH54; CTN107; CTE114; CTE112K; CTS61F; CTS106; and CTK63, Zonula occludens toxin, zot, Escherichia coli heat-labile enterotoxin, Labile Toxin, LT derivatives, LT B subunit; LT7K; LT61F; LT112K; LT118E; LT146E; LT192G; LTK63; and LTR72, Pertussis toxin, PT-9K/129G; Toxin derivatives; 25 Lipid A derivatives, MDP derivatives; Bacterial outer membrane proteins, outer surface protein A (OspA) lipoprotein of *Borrelia burgdorferi*, outer membrane protein of *Neisseria meningitidis*; Oil-in-water emulsions, Aluminum salts; and Saponins, ISCOMs, the Seppic ISA series of Montanide adjuvants, Montanide ISA 720; PROVAX; Syntext Adjuvant Formulation; poly[di(carboxylatophenoxy) phosphazene and Leishmania elongation factor.

16. The method of claim 6, wherein the therapeutic agent is a cytokine.

17. The method of claim 1, wherein the Th2-immunostimulatory nucleic acid is formulated in a form selected from the group consisting of a liquid solution, a powder, a microparticle, and a bioadhesive polymer.

5 18. The method of claim 1, wherein the Th2-immunostimulatory nucleic acid is administered by a route selected from the group consisting of oral, intranasal, vaginal, rectal, intra-ocular, and by inhalation.

10 19. The method of claim 1, wherein the Th2-immunostimulatory nucleic acid is administered by a route selected from the group consisting of intradermal, intraepidermal and transdermal.

15 20. The method of claim 1, wherein the antigen specific immune response is a systemic immune response.

21. The method of claim 1, wherein the antigen specific immune response is a mucosal immune response.

22. The method of claim 1, wherein the Th2-immunostimulatory nucleic acid is administered using a delivery system selected from the group consisting of a needleless delivery system, a scarification delivery system, and a tyne delivery system.

25 23. The method of claim 1, wherein the antigen is administered using a delivery system selected from the group consisting of a needleless delivery system, a scarification delivery system, and a tyne delivery system.

24. The method of claim 6, wherein the therapeutic agent is selected from the group consisting of an anti-viral agent, an anti-bacterial agent, an anti-parasitic agent, an anti-fungal agent, and cancer medicament.

30 25. The method of claim 1, wherein the antigen is selected from the group of antigens consisting of viral antigens, fungal antigens, bacterial antigens, parasitic antigens, and cancer antigens.

26. The method of claim 1, wherein the subject has not been exposed to an Th1 immunostimulatory nucleic acid prior to administration of the Th2 immunostimulatory nucleic acid.

5

27. The method of claim 1, wherein the subject is not experiencing a Th1 mediated disorder at the time of administration.

10 28. The method of claim 1, wherein the antigen is not conjugated to the Th2 immunostimulatory nucleic acid.

29. The method of claim 1, wherein the antigen is not a self antigen.

15 30. The method of claim 1, wherein the antigen is not an extracellular antigen.

15 31. A method for inducing an antigen specific response comprising:  
administering to a subject an antigen and a Th2-immunostimulatory nucleic acid in an amount effective to produce an antigen specific immune response when the Th2-immunostimulatory nucleic acid is administered parenterally.

20

32. The method of claim 31, wherein the subject is administered the antigen after the Th2-immunostimulatory nucleic acid.

25 33. The method of claim 31, wherein the subject is administered the antigen before the Th2-immunostimulatory nucleic acid.

34. The method of claim 31, wherein the subject is administered the antigen and the Th2-immunostimulatory nucleic acid simultaneously.

30

35. The method of claim 31, wherein the Th2-immunostimulatory nucleic acid is delivered intravenously, intraperitoneally, intramuscularly, subcutaneously, or by infusion.

36. The method of claim 31, further comprising administering a therapeutic agent to the subject.

37. The method of claim 36, wherein the therapeutic agent is a Th1 adjuvant.

5

38. The method of claim 37, wherein the Th1 adjuvant is selected from the group consisting of CpG nucleic acids, MF59, SAF, MPL, and QS21.

10

39. The method of claim 36, wherein the therapeutic agent is a Th2 adjuvant.

40. The method of claim 39, wherein the Th2 adjuvant is selected from the group consisting of adjuvants that creates a depot effect, adjuvants that stimulate the immune system, adjuvants that create a depot effect and stimulate the immune system and mucosal adjuvants.

15

41. The method of claim 40, wherein the adjuvant that creates a depot effect is selected from the group consisting of alum; emulsion-based formulations including mineral oil, non-mineral oil, water-in-oil or oil-in-water-in oil emulsion, oil-in-water emulsions such as Seppic ISA series of Montanide adjuvants; and PROVAX.

20

42. The method of claim 40, wherein the adjuvant that stimulates the immune system is selected from the group consisting of saponins purified from the bark of the *Q. saponaria* tree; poly[di(carboxylatophenoxy)phosphazene; derivatives of lipopolysaccharides, muramyl dipeptide and threonyl-muramyl dipeptide; OM-174; and Leishmania elongation factor.

25

43. The method of claim 40, wherein the adjuvant that creates a depot effect and stimulates the immune system is selected from the group consisting of ISCOMs; SB-AS2; SB-AS4; non-ionic block copolymers that form micelles such as CRL 1005; and Syntex Adjuvant Formulation.

30

44. The method of claim 40, wherein the mucosal adjuvant is selected from the group consisting of CpG nucleic acids, Bacterial toxins, Cholera toxin, CT derivatives, CT B subunit; CTD53; CTK97; CTK104; CTD53/K63; CTH54; CTN107; CTE114; CTE112K;

CTS61F; CTS106; and CTK63, Zonula occludens toxin, zot, Escherichia coli heat-labile enterotoxin, Labile Toxin, LT derivatives, LT B subunit; LT7K; LT61F; LT112K; LT118E; LT146E; LT192G; LTK63; and LTR72, Pertussis toxin, PT-9K/129G; Toxin derivatives; Lipid A derivatives, MDP derivatives; Bacterial outer membrane proteins, outer surface protein A (OspA) lipoprotein of *Borrelia burgdorferi*, *outer membrane protein of Neisseria meningitidis*; Oil-in-water emulsions, Aluminum salts; and Saponins, ISCOMs, the Seppic ISA series of Montanide adjuvants, Montanide ISA 720; PROVAX; Syntext Adjuvant Formulation; poly[di(carboxylatophenoxy) phosphazene and Leishmania elongation factor.

10 45. The method of claim 36, wherein the therapeutic agent is a cytokine.

46. The method of claim 31, wherein the Th2-immunostimulatory nucleic acid is formulated in a form selected from the group consisting of a liquid solution, a powder, a microparticle, and a bioadhesive polymer.

15 47. The method of claim 31, wherein the antigen is a non-extracellular antigen.

48. The method of claim 31, wherein the antigen specific immune response is a systemic immune response.

20 49. The method of claim 31, wherein the antigen is administered using a delivery system selected from the group consisting of a needleless delivery system, a scarification delivery system, and a tyne delivery system.

25 50. The method of claim 36, wherein the therapeutic agent is selected from the group consisting of an anti-viral agent, an anti-bacterial agent, an anti-parasitic agent, an anti-fungal agent, and cancer medicament.

30 51. The method of claim 31, wherein the antigen is selected from the group of antigens consisting of viral antigens, fungal antigens, yeast antigens, parasitic antigens, and tumor (i.e., cancer) antigens.

52. The method of claim 31, wherein the subject has not been exposed to an Th1 immunostimulatory nucleic acid prior to administration of the Th2 immunostimulatory nucleic acid.

5 53. The method of claim 31, wherein the antigen is not conjugated to the Th2 immunostimulatory nucleic acid.

54. The method of claim 31, wherein the antigen is not a self antigen.

10 55. A method for treating a non-autoimmune Th1-mediated disease, comprising: administering to a subject a Th2 immunostimulatory nucleic acid in an amount effective to produce a Th2 immune response when administered mucosally or dermally.

15 56. The method of claim 55, wherein an antigen is not administered to the subject.

57. The method of claim 55, wherein the subject has not been exposed to a Th1 immunostimulatory nucleic acid.

20 58. The method of claim 55, wherein the non-autoimmune Th1-mediated disease is not mediated by a Th1 immunostimulatory nucleic acid.

25 59. The method of claim 56, wherein the disorder is selected from the group consisting of psoriasis, Th1 inflammatory disorders, solid organ allograft rejection, symptoms associated with Hepatitis B infection, insulin-dependent diabetes mellitus, multiple sclerosis, “Silent thyroiditis”, and unexplained recurrent abortion.

60. The method of claim 55, wherein the method is a method for inducing a local Th2 environment in the subject.

30 61. The method of claim 60, wherein the local Th2 environment is in the skin and wherein the subject has a Th1 mediated skin disorder.

62. The method of claim 60, wherein the local Th2 environment is in the eye and the subject has a viral infection.

63. The method of claim 62, wherein the viral infection is HSV-1.

5

64. The method of claim 55, wherein the Th2-immunostimulatory nucleic acid is administered locally.

10 65. The method of claim 64, wherein the Th2-immunostimulatory nucleic acid is administered to a tissue selected from the group consisting of skin and eye.

66. The method of claim 55, further comprising administering a therapeutic agent to the subject.

15 67. The method of claim 66, wherein the therapeutic agent is a Th1 adjuvant.

68. The method of claim 67, wherein the Th1 adjuvant is selected from the group consisting of CpG nucleic acids, MF59, SAF, MPL, and QS21.

20 69. The method of claim 66, wherein the therapeutic agent is a Th2 adjuvant.

70. The method of claim 69, wherein the Th2 adjuvant is selected from the group consisting of adjuvants that creates a depot effect, adjuvants that stimulate the immune system, adjuvants that create a depot effect and stimulate the immune system and mucosal adjuvants.

25 71. The method of claim 70, wherein the adjuvant that creates a depot effect is selected from the group consisting of alum; emulsion-based formulations including mineral oil, non-mineral oil, water-in-oil or oil-in-water-in oil emulsion, oil-in-water emulsions such as Seppic ISA series of Montanide adjuvants; and PROVAX.

30 72. The method of claim 70, wherein the adjuvant that stimulates the immune system is selected from the group consisting of saponins purified from the bark of the *Q. saponaria*

tree; poly[di(carboxylatophenoxy)phosphazene; derivatives of lipopolysaccharides, muramyl dipeptide and threonyl-muramyl dipeptide; OM-174; and Leishmania elongation factor.

73. The method of claim 70, wherein the adjuvant that creates a depot effect and  
5 stimulates the immune system is selected from the group consisting of ISCOMs; SB-AS2;  
SB-AS4; non-ionic block copolymers that form micelles such as CRL 1005; and Syntex  
Adjuvant Formulation.

74. The method of claim 70, wherein the mucosal adjuvant is selected from the group  
10 consisting of CpG nucleic acids, Bacterial toxins, Cholera toxin, CT derivatives, CT B  
subunit; CTD53; CTK97; CTK104; CTD53/K63; CTH54; CTN107; CTE114; CTE112K;  
CTS61F; CTS106; and CTK63, Zonula occludens toxin, zot, Escherichia coli heat-labile  
enterotoxin, Labile Toxin, LT derivatives, LT B subunit; LT7K; LT61F; LT112K; LT118E;  
LT146E; LT192G; LTK63; and LTR72, Pertussis toxin, PT-9K/129G; Toxin derivatives;  
15 Lipid A derivatives, MDP derivatives; Bacterial outer membrane proteins, outer surface  
protein A (OspA) lipoprotein of *Borrelia burgdorferi*, *outer membrane protein of Neisseria*  
*meningitidis*; Oil-in-water emulsions, Aluminum salts; and Saponins, ISCOMs, the Seppic  
ISA series of Montanide adjuvants, Montanide ISA 720; PROVAX; Syntext Adjuvant  
Formulation; poly[di(carboxylatophenoxy) phosphazene and Leishmania elongation factor.  
20

75. The method of claim 66, wherein the therapeutic agent is a cytokine.

76. The method of claim 66, wherein the therapeutic agent is a drug for treating Th1  
mediated disorders.

25 77. The method of claim 76, wherein the drug for treating Th1 mediated disorders is  
selected from the group consisting of anti-psoriasis creams, eye drops, nose drops,  
Sulfasalazine, glucocorticoids, propylthiouracil, methimazole, <sup>131</sup>I, insulin, IFN- $\beta$ 1a, IFN-  
 $\beta$ 1b, copolymer 1 (i.e., MS), glucocorticoids (i.e., MS), ACTH, avonex, azathioprine,  
30 cyclophosphamide, UV-B, PUVA, methotrexate, calcipitriol, cyclophosphamide, OKT3, FK-  
506, cyclosporin A, azathioprine, and mycophenolate mofetil.

78. A method for treating an autoimmune disease, comprising:

administering to a subject a Th2-immunostimulatory nucleic acid in an amount effective to produce a Th2 immune response when administered mucosally or dermally, wherein the subject has not been exposed to a Th1 immunostimulatory nucleic acid.

5        79. The method of claim 78, wherein the autoimmune disease is selected from the group consisting of rheumatoid arthritis, Crohn's disease, systemic lupus erythematosus (SLE), autoimmune encephalomyelitis, myasthenia gravis, Hashimoto's thyroiditis, Goodpasture's syndrome, pemphigus, Grave's disease, autoimmune hemolytic anemia, autoimmune thrombocytopenic purpura, scleroderma with anti-collagen antibodies, mixed 10 connective tissue disease, polymyositis, pernicious anemia, idiopathic Addison's disease, autoimmune-associated infertility, glomerulonephritis, bullous pemphigoid, Sjögren's syndrome, insulin resistance, and autoimmune diabetes mellitus.

15        80. The method of claim 78, further comprising administering to the subject a self antigen, to produce an immune hyporesponsive state.

20        81. The method of claim 80, wherein the self antigen is not conjugated to the Th2 immunostimulatory nucleic acid.

25        82. The method of claim 78, wherein the method is a method for inducing a local Th2 environment in the subject.

83. The method of claim 82, wherein the local Th2 environment is in the skin.

25        84. The method of claim 82, wherein the local Th2 environment is in the eye.

85. The method of claim 78, wherein the Th2-immunostimulatory nucleic acid is administered mucosally.

30        86. The method of claim 78, wherein the Th2-immunostimulatory nucleic acid is administered locally.

87. The method of claim 86, wherein the Th2-immunostimulatory nucleic acid is administered to a tissue selected from the group consisting of skin and eye.

88. The method of claim 78, further comprising administering a therapeutic agent to  
5 the subject.

89. The method of claim 88, wherein the therapeutic agent is a Th1 adjuvant.

90. The method of claim 89, wherein the Th1 adjuvant is selected from the group  
10 consisting of CpG nucleic acids, MF59, SAF, MPL, and QS21.

91. The method of claim 88, wherein the therapeutic agent is a Th2 adjuvant.

92. The method of claim 91, wherein the Th2 adjuvant is selected from the group  
15 consisting of adjuvants that creates a depot effect, adjuvants that stimulate the immune system, adjuvants that create a depot effect and stimulate the immune system and mucosal adjuvants.

93. The method of claim 92, wherein the adjuvant that creates a depot effect is  
20 selected from the group consisting of alum; emulsion-based formulations including mineral oil, non-mineral oil, water-in-oil or oil-in-water-in oil emulsion, oil-in-water emulsions such as Seppic ISA series of Montanide adjuvants; and PROVAX.

94. The method of claim 92, wherein the adjuvant that stimulates the immune system  
25 is selected from the group consisting of saponins purified from the bark of the *Q. saponaria* tree; poly[di(carboxylatophenoxy)phosphazene; derivatives of lipopolysaccharides, muramyl dipeptide and threonyl-muramyl dipeptide; OM-174; and Leishmania elongation factor.

95. The method of claim 92, wherein the adjuvant that creates a depot effect and  
30 stimulates the immune system is selected from the group consisting of ISCOMs; SB-AS2; SB-AS4; non-ionic block copolymers that form micelles such as CRL 1005; and Syntex Adjuvant Formulation.

96. The method of claim 92, wherein the mucosal adjuvant is selected from the group consisting of CpG nucleic acids, Bacterial toxins, Cholera toxin, CT derivatives, CT B subunit; CTD53; CTK97; CTK104; CTD53/K63; CTH54; CTN107; CTE114; CTE112K; CTS61F; CTS106; and CTK63, Zonula occludens toxin, zot, Escherichia coli heat-labile 5 enterotoxin, Labile Toxin, LT derivatives, LT B subunit; LT7K; LT61F; LT112K; LT118E; LT146E; LT192G; LTK63; and LTR72, Pertussis toxin, PT-9K/129G; Toxin derivatives; Lipid A derivatives, MDP derivatives; Bacterial outer membrane proteins, outer surface 10 protein A (OspA) lipoprotein of *Borrelia burgdorferi*, outer membrane protein of *Neisseria meningitidis*; Oil-in-water emulsions, Aluminum salts; and Saponins, ISCOMs, the Seppic ISA series of Montanide adjuvants, Montanide ISA 720; PROVAX; Syntext Adjuvant Formulation; poly[di(carboxylatophenoxy) phosphazene and Leishmania elongation factor.

97. The method of claim 88, wherein the therapeutic agent is a cytokine.

15 98. The method of claim 88, wherein the therapeutic agent is a drug for treating autoimmune disease.

99. The method of claim 98, wherein the drug for treating Th1 mediated disorders is selected from the group consisting of anti-psoriasis creams, eye drops, nose drops, 20 Sulfasalazine, glucocorticoids, propylthiouracil, methimazole, <sup>131</sup>I, insulin, IFN- $\beta$ 1a, IFN- $\beta$ 1b, copolymer 1 (i.e., MS), glucocorticoids (i.e., MS), ACTH, avonex, azathioprine, cyclophosphamide, UV-B, PUVA, methotrexate, calcipitriol, cyclophosphamide, OKT3, FK-506, cyclosporin A, azathioprine, and mycophenolate mofetil.

25 100. A pharmaceutical composition, comprising:  
an effective amount of a Th2 immunostimulatory nucleic acid for stimulating a Th2 immune response when administered mucosally or dermally, an antigen, and a pharmaceutically acceptable carrier.

30 101. The pharmaceutical composition of claim 100, wherein the antigen is not conjugated to the Th2 immunostimulatory nucleic acid.

102. The pharmaceutical composition of claim 100, wherein the Th2 immune response is a mucosal immune response.

103. The pharmaceutical composition of claim 100, wherein the Th2 immune 5 response is a systemic immune response.

104. The pharmaceutical composition of claim 100, wherein the antigen is not an self antigen.

10 105. The pharmaceutical composition of claim 100, wherein the Th2-immunostimulatory nucleic acid is formulated in a delivery vehicle selected from the group consisting of bioadhesive polymers, cochleates, dendrimers, enteric-coated capsules, emulsomes, ISCOMs, liposomes, cationic lipids, microspheres, nanospheres, polymer rings, proteosomes, and virosomes.

15 106. The pharmaceutical composition of claim 100, further comprising a therapeutic agent.

20 107. The pharmaceutical composition of claim 106, wherein the therapeutic agent is a Th1 adjuvant.

108. The pharmaceutical composition of claim 106, wherein the therapeutic agent is a Th2 adjuvant.

25 109. The pharmaceutical composition of claim 106, wherein the therapeutic agent is a cytokine.

110. The pharmaceutical composition of claim 106, wherein the therapeutic agent is a drug for treating Th1 mediated disorders.

30 111. The pharmaceutical composition of claim 105, wherein the Th2-immunostimulatory nucleic acid and antigen are present in different delivery vehicles.

112. A pharmaceutical composition, comprising:

an effective amount of a Th2 immunostimulatory nucleic acid for stimulating a Th2 immune response when administered mucosally or dermally, and an adjuvant, in a pharmaceutically acceptable carrier.

5

113. The pharmaceutical composition of claim 112, wherein the Th2 immune response is a mucosal immune response.

10 114. The pharmaceutical composition of claim 112, wherein the Th2 immune response is a systemic immune response.

115. The pharmaceutical composition of claim 112, wherein the adjuvant is a Th1 adjuvant.

15 116. The pharmaceutical composition of claim 112, wherein the Th1 adjuvant is selected from the group consisting of CpG nucleic acids, MF59, SAF, MPL, and QS21.

117. The pharmaceutical composition of claim 112, wherein the adjuvant is a Th2 adjuvant.

20 118. The pharmaceutical composition of claim 117, wherein the Th2 adjuvant is selected from the group consisting of adjuvants that creates a depot effect, adjuvants that stimulate the immune system, adjuvants that create a depot effect and stimulate the immune system and mucosal adjuvants.

25

119. The pharmaceutical composition of claim 118, wherein the adjuvant that creates a depot effect is selected from the group consisting of alum; emulsion-based formulations including mineral oil, non-mineral oil, water-in-oil or oil-in-water-in oil emulsion, oil-in-water emulsions such as Seppic ISA series of Montanide adjuvants; and PROVAX.

30

120. The pharmaceutical composition of claim 118, wherein the adjuvant that stimulates the immune system is selected from the group consisting of saponins purified from the bark of the *Q. saponaria* tree; poly[di(carboxylatophenoxy)phosphazene; derivatives of

lipopolysaccharides, muramyl dipeptide and threonyl-muramyl dipeptide; OM-174; and Leishmania elongation factor.

121. The pharmaceutical composition of claim 118, wherein the adjuvant that creates  
5 a depot effect and stimulates the immune system is selected from the group consisting of ISCOMs; SB-AS2; SB-AS4; non-ionic block copolymers that form micelles such as CRL 1005; and Syntex Adjuvant Formulation.

122. The pharmaceutical composition of claim 118, wherein the mucosal adjuvant is  
10 selected from the group consisting of CpG nucleic acids, Bacterial toxins, Cholera toxin, CT derivatives, CT B subunit; CTD53; CTK97; CTK104; CTD53/K63; CTH54; CTN107; CTE114; CTE112K; CTS61F; CTS106; and CTK63, Zonula occludens toxin, zot, Escherichia coli heat-labile enterotoxin, Labile Toxin, LT derivatives, LT B subunit; LT7K; LT61F; LT112K; LT118E; LT146E; LT192G; LTK63; and LTR72, Pertussis toxin, PT-  
15 9K/129G; Toxin derivatives; Lipid A derivatives, MDP derivatives; Bacterial outer membrane proteins, outer surface protein A (OspA) lipoprotein of *Borrelia burgdorferi*, outer membrane protein of *Neisseria meningitidis*; Oil-in-water emulsions, Aluminum salts; and Saponins, ISCOMs, the Seppic ISA series of Montanide adjuvants, Montanide ISA 720; PROVAX; Syntext Adjuvant Formulation; poly[di(carboxylatophenoxy) phosphazene and  
20 Leishmania elongation factor.

123. The pharmaceutical composition of claim 112, further comprising a therapeutic agent selected from the group consisting of an anti-viral agent, an anti-bacterial agent, an anti-parasitic agent, an anti-fungal agent, and a cancer medicament.

25 124. A method for treating an infectious disease in a subject, comprising:  
administering to a subject having an infectious disease a Th2 immunostimulatory nucleic acid in an amount effective to treat the infectious disease when administered mucosally, dermally, or parenterally, wherein the subject has not been exposed to a Th1 immunostimulatory nucleic acid.

125. The method of claim 124, wherein the infectious disease is not an extracellular infection.

126. The method of claim 124, wherein the method is a method for treating a viral infection.

5 127. The method of claim 126, further comprising, administering an anti-viral agent.

128. The method of claim 124, wherein the method is a method for treating or preventing a bacterial infection.

10 129. The method of claim 128, further comprising, administering an anti-bacterial agent.

130. The method of claim 124, wherein the method is a method for treating or preventing a parasitic infection.

15 131. The method of claim 130, further comprising administering an anti-parasitic agent.

132. The method of claim 124, wherein the Th2 immunostimulatory nucleic acid is 20 administered mucosally

133. The method of claim 124, wherein the Th2 immunostimulatory nucleic acid is administered locally.

25 134. The method of claim 124, wherein the Th2 immunostimulatory nucleic acid is administered parenterally.

135. A method of preventing an infectious disease in a subject, comprising 30 administering to a subject at risk of developing an infectious disease a Th2 immunostimulatory nucleic acid in an amount effective to prevent the infectious disease when administered mucosally, dermally, or parenterally, wherein the subject has not been exposed to a Th1 immunostimulatory nucleic acid.

136. A method for treating or preventing a cancer in a subject, comprising:  
administering to a subject having a cancer or at risk of developing a cancer a Th2  
immunostimulatory nucleic acid in an amount effective to treat or prevent the cancer when  
administered mucosally, dermally, or parenterally.

5

137. The method of claim 136, wherein the cancer is a cancer selected from the group  
consisting of oral cavity cancer, throat cancer, stomach cancer, colon cancer, rectal cancer,  
cervical cancer.

10

138. The method of claim 136, wherein the Th2-immunostimulatory nucleic acid is  
administered mucosally

139. The method of claim 136, wherein the Th2-immunostimulatory nucleic acid is  
administered locally.

15

140. The method of claim 136, wherein the Th2-immunostimulatory nucleic acid is  
administered parenterally.

20

141. The method of claim 136, further comprising administering an anti-cancer agent.

142. A method for stimulating an antibody dependent cellular cytotoxic (ADCC)  
immune response in a subject, comprising administering to the subject a Th2  
immunostimulatory nucleic acid and an antibody in an effective amount for inducing ADCC.

25

143. The method of claim 142, wherein the antibody is a monoclonal antibody.

30

144. The method of claim 142, wherein the monoclonal antibody is selected from the  
group consisting of Rituxan, IDEC-C2B8, anti-CD20 Mab, Panorex, 3622W94, anti-EGP40  
(17-1A) pancarcinoma antigen on adenocarcinomas Herceptin, anti-Her2, Anti-EGFr, BEC2,  
anti-idiotypic-GD<sub>3</sub> epitope, Ovarex, B43.13, anti-idiotypic CA125, 4B5, Anti-VEGF,  
RhuMAb, MDX-210, anti-HER-2, MDX-22, MDX-220, MDX-447, MDX-260, anti-GD-2,  
Quadramet, CYT-424, IDEC-Y2B8, Oncolym, Lym-1, SMART M195, ATRAGEN, LDP-  
03, anti-CAMPATH, ior t6, anti CD6, MDX-11, OV103, Zenapax, Anti-Tac, anti-IL-2

2025 RELEASE UNDER E.O. 14176

receptor, MELIMMUNE-2, MELIMMUNE-1, CEACIDE, Pretarget, NovoMAb-G2, TNT, anti-histone, Gliomab-H, GNI-250, EMD-72000, LymphoCide, CMA 676, Monopharm-C, ior egf/r3, ior c5, anti-FLK-2, SMART 1D10, SMART ABL 364, and ImmuRAIT-CEA.

5 145. The method of claim 142, wherein the subject has a disorder selected from the group consisting of cancer, and infectious disease.

146. The method of claim 142, wherein the Th2 immunostimulatory nucleic acid is not conjugated to the antibody.

10

147. The method of claim 142, wherein the subject has a cancer.

148. The method of claim 147, further comprising administering radiation or chemotherapy to the subject.

15

149. The method of claim 148, wherein the chemotherapy is selected from the group consisting of Taxol, cisplatin, doxorubicin, and adriamycin.

20

150. A pharmaceutical composition, comprising:

a Th2 immunostimulatory nucleic acid in an effective amount for inducing

ADCC, a monoclonal antibody, and a pharmaceutically acceptable carrier.

25

151. The composition of claim 150, wherein the monoclonal antibody is selected from the group consisting of Rituxan, IDEC-C2B8, anti-CD20 Mab, Panorex, 3622W94, anti-EGP40 (17-1A) pancarcinoma antigen on adenocarcinomas Herceptin, anti-Her2, Anti-EGFr, BEC2, anti-idiotypic-GD<sub>3</sub> epitope, Ovarex, B43.13, anti-idiotypic CA125, 4B5, Anti-VEGF, RhuMAb, MDX-210, anti-HER-2, MDX-22, MDX-220, MDX-447, MDX-260, anti-GD-2, Quadramet, CYT-424, IDEC-Y2B8, Oncolym, Lym-1, SMART M195, ATRAGEN, LDP-03, anti-CAMPATH, ior t6, anti CD6, MDX-11, OV103, Zenapax, Anti-Tac, anti-IL-2 receptor, MELIMMUNE-2, MELIMMUNE-1, CEACIDE, Pretarget, NovoMAb-G2, TNT, anti-histone, Gliomab-H, GNI-250, EMD-72000, LymphoCide, CMA 676, Monopharm-C, ior egf/r3, ior c5, anti-FLK-2, SMART 1D10, SMART ABL 364, and ImmuRAIT-CEA.

RECEIVED  
U.S. PATENT AND  
TRADEMARK OFFICE  
JULY 10 2008  
10:00 AM  
PTAB

152. A composition, comprising:

a Th2 immunostimulatory nucleic acid having a phosphodiester backbone, formulated in a delivery vehicle selected from the group consisting of bioadhesive polymers, enteric-coated capsules, microspheres, nanospheres, and polymer rings.

5

153. The composition of claim 152, wherein the Th2 immunostimulatory nucleic acid is formulated for mucosal delivery.